**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

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| MALKA and MOSHE MANDEL,<br><br>Plaintiffs,<br><br>v.<br><br>COCHLEAR LIMITED, an Australian Public Company and COCHLEAR AMERICAS CORPORATION, a Delaware Corporation,<br><br>Defendants. | ) | **Case No. _____**<br><br>**JURY TRIAL DEMANDED** |

**COMPLAINT**

1. Plaintiffs MALKA MANDEL and MOSHE MANDEL bring this action because a Cochlear Nucleus CI512 cochlear implant medical device manufactured, distributed, and sold by defendants, Cochlear Limited and Cochlear Americas Corporation (the "Cochlear Implant"), failed after it was surgically implanted into plaintiff Malka Mandel's body, requiring further surgery in an attempt to restore some part of her hearing.

2. The Cochlear Nucleus C1500 range of cochlear implant medical devices, which includes the Cochlear Nucleus C1512 model that Malka Mandel received, were subject to a global recall issued in October 2011, due to an increase in the number of Cochlear Nucleus CI512 implant failures.

3. The United States Food and Drug Administration ("FDA") had previously approved a certain design, materials, construction, manufacturing method, testing, and labeling

of defendants' Cochlear Nucleus CI512 cochlear implant medical device pursuant to that agency's premarket approval process ("PMA").

4. Specifically, defendants' Cochlear Nucleus CI512 cochlear implant medical device was approved as a supplement to PMA P970051, which was originally approved by the FDA on or about June 25, 1998. The PMA supplement for defendant's Cochlear Nucleus CI512 was approved by the FDA on August 28, 2009.

5. As is more fully set forth herein, defendants failed to comply with the specifications and requirements of the PMA, federal law and federal regulations. As a result, plaintiff Malka Mandel suffered personal injuries, and plaintiffs Malka and Moshe Mandel suffered economic losses and emotional distress as a result of the injuries to Malka Mandel.

6. As a result of the defendants' failure to comply with the specifications and requirements of the PMA, federal law and federal regulations, the Cochlear Nucleus CI500 range of cochlear implant medical devices, including the Cochlear Nucleus CI512, were subject to a global recall issued in October 2011.

7. This recall was predicated upon defendants' knowledge that their Cochlear Nucleus CI512 series had experienced an increased failure rate as result of "hermeticity" or sealing compromises in the Cochlear Nucleus CI512 devices, and that these failures were caused by inexcusable manufacturing defects resulting from defendants' failure to comply with the specifications and requirements of the PMA, federal law and federal regulations. These same defects caused the failure of plaintiff Malka Mandel's Cochlear Implant as a result of "hermeticity" or sealing compromises.

8. As more fully set forth herein, defendants knowingly exposed Malka Mandel to the risk of medical device failure, corrective surgery and personal injury, among other things, as

a result of defendants' failure to comply with the specifications and requirements of the PMA, federal law and federal regulations.

9. Plaintiffs' claims are premised entirely on defendants' failure to comply with the PMA, federal law, and federal regulations, subjecting defendants to liability for plaintiffs' parallel state law claims set forth herein.

10. Plaintiffs' parallel state law claims set forth herein will not impose any requirement or standard relating to the safety or effectiveness of the Cochlear Nucleus CI512 cochlear implant medical device, or any other matter regulated by the FDA, that is different from, or in addition to, any requirement applicable to the Cochlear Nucleus CI512 cochlear implant medical device under the PMA, federal law or federal regulations.

11. Plaintiffs do not challenge the FDA's approval of the design, manufacturing process, or labeling of a premarket approved medical device in this action. Rather, by pursuing their parallel state law claims set forth herein, plaintiffs seek to hold defendants responsible for their injuries and damages proximately caused by the defendants' failure to comply with the specifications and requirements of the PMA, federal law and federal regulations with respect to the Cochlear Implant.

12. Plaintiffs do not claim herein that the Cochlear Implant should have been designed, manufactured, tested, marketed, or labeled in a manner different from that approved by the FDA.

13. Rather, as more fully set forth herein, plaintiffs claim that, with respect to the Cochlear Implant, defendants' failure to comply with the specifications and requirements of the PMA, federal law, and federal regulations proximately caused them to suffer injuries and damages of a personal and pecuniary nature.

14. As more fully set forth herein, the Cochlear Implant that plaintiff Malka Mandel received was not manufactured according to the specifications and requirements of the PMA, federal law, and federal regulations; and therefore was not the Class III medical device approved by the FDA.

**Parties**

15. Plaintiff, Malka Mandel is a United States citizen and a citizen of the State of New Jersey, domiciled in Lakewood, Ocean County, New Jersey.

16. Plaintiff, Moshe Mandel is a United States citizen and a citizen of the State of New Jersey, domiciled in Lakewood, Ocean County, New Jersey.

17. Defendant Cochlear Limited ("Cochlear") is an Australian public company with its principal place of business in New South Wales, Australia.

18. Defendant Cochlear Americas Corporation ("CAM") is a Delaware corporation with its principal place of business in Centennial, Colorado.

19. CAM is a wholly owned subsidiary of Cochlear.

20. Cochlear established and maintains that CAM as its wholly owned subsidiary for the purpose of conducting business on behalf of and for the benefit of Cochlear in the United States, including in the forum state of New York.

21. Cochlear established and maintains CAM to create, control, and employ the distribution systems that bring Cochlear's products into the United States, including the Cochlear Implant into the forum state of New York.

22. At all times relevant, Cochlear, through its directors, officers, employees, and agents, had actual knowledge that products that it manufactured, including the Cochlear Implant, were being marketed and sold in the forum state of New York.

23. At all times relevant herein, CAM's actions in the United States, including in the forum state of New York, on behalf of and for the benefit of Cochlear, include sales, marketing, distribution, service, finance, regulatory and administration of Cochlear's products, including the Cochlear Implant.

24. At all times relevant, the products that Cochlear manufactures, including the Cochlear Implant, have been sold and distributed exclusively in the United States through CAM.

25. At all times relevant, CAM has only sold, marketed, distributed, serviced, and sought regulatory approval for products manufactured by its parent corporation, Cochlear.

26. In furtherance of selling its Class III medical devices, including the Cochlear Implant, in the United States generally, and in the forum state of New York, specifically, Cochlear obtained federal regulatory approval from the FDA.

## Jurisdiction and Venue

27. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a) because there is complete diversity of citizenship between plaintiffs and defendants, and the amount in controversy, exclusive of interest and costs, exceeds $75,000.

28. Venue is proper in this district pursuant to 28 U.S.C. §1391(b)(2), because a substantial part of the events or omissions giving rise to plaintiffs' claims occurred in this district, including plaintiff's receipt of and implantation with the Cochlear Implant in New York, New York.

29. Defendants are subject to personal jurisdiction in this district because plaintiffs' claims arise from defendants' actions in transacting business in the State of New York, and defendants' commission of tortious acts in the State of New York.

30. Defendants are subject to personal jurisdiction in this district in accordance with New York's long-arm statute and federal constitutional requirements because they have both purposefully availed themselves of the forum state of New York's benefits, and plaintiffs' claims complained of herein arise out of and/or relate to both defendants' transaction of business within the State of New York, and defendants' commission of tortious acts within the State of New York.

## FACTUAL BACKGROUND

### The Cochlear Implants

31. The Cochlear Implants are surgically implanted medical devices that provide a sense of sound to people who are either profoundly deaf or severely hard of hearing.

32. The Cochlear Implants' system contains both internal and external components.

33. The Cochlear Implants' system's external components include a sound processor and magnetic coil that are worn behind the ear.

34. The Cochlear Implants system's internal components include a receiver/stimulator that is housed in what is designed as, and intended to be, a hermetically sealed (i.e. moisture impervious) titanium chassis; a platinum receiver coil; and an intra-cochlear electrode array. The internal components are surgically implanted under the skin behind the ear, and into the cochlea (inner ear).

35. The Cochlear Implants' internal receiver/stimulator contains feedthrough assembly to allow for contact between the internal electrical components and the external components.

36. The Cochlear Implants convert sound into electrical energy that activates the auditory nerve. The auditory nerve then sends the information to the brain, where it is interpreted as sound.

**The Cochlear Implants' Failure and Recall**

37. On or about October 3, 2011, the FDA issued a Class 2 Recall, pursuant to Recall Number Z-0003-2012, for the Cochlear Nucleus CI512 Cochlear Implant, REF Z209051, New with Nucleus 5, Sterile EO.

38. According to the FDA's October 3, 2011 recall, the Recalled Devices were intended to restore a level of auditory sensation via the electrical stimulation of the auditory nerve.

39. According to the FDA's recall, the reason for the recall was that the Recalled Devices may shut down and cease to function.

40. According to the FDA's recall, there was worldwide distribution of the Recalled Devices, including nationwide distribution in the United States.

41. On or about December 16, 2011, defendant's CEO and president, Dr. Chris Roberts, released a letter advising that:

> "This letter updates progress on investigations associated with the voluntary recall of unimplanted CI500 series implants, specifically information on the root cause of the loss of hermeticity.
>
> The results of our investigation to date point to a loss of hermeticity from unexpected variations in the brazing process during manufacturing. Brazing is the process that joins the feedthrough to the titanium chassis. Variations in the brazing process have resulted in a limited number of implants being more susceptible to developing microcracks in the braze joint during subsequent manufacturing steps. These microcracks allow water molecules to enter the implant resulting in the malfunction of specific electronic components (typically one of four diodes).

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> The overall proportion of CI500 series devices that has failed is approximately 1.9% of registered implants globally with similar percentages in all three regions (The Americas, Europe Middle East & Africa (EMEA) and Asia Pacific). There were fewer reported failures in November 2011 than in October 2011."

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42. On or about February 6, 2012, defendant's CEO and president, Dr. Chris Roberts, released a letter advising, among other things, that:

> "This letter provides the latest information regarding the voluntary recall of unimplanted Nucleus CI500 series implants, specifically information regarding the latest observations associated with the number of reported devices failing, the failure mechanism and the clinical symptoms associated with the failure mechanism.
>
> In December 2011, we reported the root cause for the loss of hermeticity to be unexpected variations in the brazing process that joints the feedthrough to the titanium chassis during manufacturing. These variations resulted in a limited number of implants being more susceptible to developing microcracks in the braze joint during subsequent manufacturing steps. These microcracks allow water molecules to enter the implant resulting in the malfunction of specific electronic components (typically one of four diodes). Failure of these electronic components results in the implant shutting down. This failure mechanism continues to be consistent with no other failure mechanism associated with the loss of hermeticity identified.
>
> As of January 31st, 2012, the overall proportion of Nucleus CI500 series devices that has been reported as failed is 2.4% of registered devices globally…"

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**Facts Regarding Plaintiff**

43. Plaintiff has at all times relevant herein suffered from substantial hearing loss.

44. Plaintiff was medically evaluated for a cochlear implant medical device and determined to be an excellent candidate to receive a cochlear implant.

45. On or about April 6, 2011, plaintiff was surgically implanted with the Cochlear Implant designed, manufactured, marketed, sold, and distributed by defendants.

46. Subsequently, plaintiff's cochlear implant failed.

47. Upon information and belief, plaintiff's Cochlear Implant failed due to an electronic failure resulting from a loss of hermeticity (i.e. failure of the moisture impervious seal) of the titanium chassis of the Cochlear Implant's internal receiver/stimulator.

48. Upon information and belief, this loss of hermeticity in plaintiff's Cochlear Implant's internal receiver/stimulator resulted from unintended variations in the brazing process that occurred during the manufacture of plaintiff's Cochlear Implant.

49. Upon information and belief, brazing was the process that joined the feedthrough of plaintiff's Cochlear Implant to its respective titanium chassis.

50. Upon information and belief, these unintended variations in the brazing process during the manufacture of plaintiff's cochlear implant resulted in plaintiff's cochlear implant being more susceptible to developing microcracks in the braze joint during subsequent manufacturing steps.

51. Upon information and belief, microcracks developed in the braze joint of plaintiff's cochlear implant during its manufacturing process, as a result of the unintended variations in the brazing process.

52. Upon information and belief, these microcracks in the braze joint of plaintiff's cochlear implant allowed water molecules to enter plaintiff's Cochlear Implant and cause a malfunction of certain electronic components contained in the Cochlear Implant.

53. Upon information and belief, defendants failed to detect the microcracks in the braze joint of plaintiff's Cochlear Implant during its manufacturing process and related testing.

54. Upon information and belief, these microcracks in plaintiff's Cochlear Implant braze joint existed at the time that plaintiff's Cochlear Implant left the hands of the defendants.

55. On or about October 22, 2015, plaintiff's Cochlear Implant was surgically explanted from her body due to the electronic failure resulting from the loss of hermeticity due to unintended variations in the brazing process that occurred during the manufacture of plaintiff's Cochlear Implant.

**Federal Requirements**

56. The Recalled Devices are Class III medical devices regulated by the FDA.

57. A medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, of if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. §351.

58. A medical device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. §352.

59. Medical device manufacturers such as defendant are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introductions of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices.

60. In particular, medical device manufacturers such as defendant must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury.

61. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device, such as defendant, to report promptly to FDA any correction

or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. § 360i.

62. The Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device to conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. 21 U.S.C. §360j(f).

63. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR §820 et seq. As explained in the Federal Register, because Current Good Manufacturing Practice ("CGMP") regulations apply to a variety of medical devices, the regulations do not prescribe the exact details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of minimum requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the minimum requirements set forth in the quality system regulations.

64. Pursuant to 21 CFR §820.1(c), the failure to comply with the provisions in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. §351).

65. Pursuant to 21 CFR §820.5, each manufacturer of a medical device, such as defendant, shall establish and maintain a quality system that is appropriate for the specific

medical device designed and manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. See 21 CFR §820.3(v).

66. Pursuant to 21 CFR §820.22, each manufacturer of a medical device, such as defendant, shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

67. Pursuant to 21 CFR §820.30(a), each manufacturer of a medical device, such as defendant, shall establish and maintain procedures to control the design of a device in order to ensure that specified design requirements are met.

68. Pursuant to 21 CFR §820.30(d), each manufacturer of a medical device, such as defendant, shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

69. Pursuant to 21 CFR §820.30(e), each manufacturer of a medical device, such as defendant, shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

70. Pursuant to 21 CFR §820.30(f), each manufacturer of a medical device, such as defendant, shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

71. Pursuant to 21 CFR §820.30(h), each manufacturer of a medical device, such as defendant, shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

72. Pursuant to 21 CFR §820.30(i), each manufacturer of a medical device, such as defendant, shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review and approval of design changes before their implementation.

73. Pursuant to 21 CFR §820.70(a), each manufacturer of a medical device, such as defendant, shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that described any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a. Documented instructions, standard operating procedures ("SOP""s), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

74. Pursuant to 21 CFR §820.70(b), each manufacturer of a medical device, such as defendants, shall establish and maintain procedures for changes to a specification, method, process or procedure.

75. Pursuant to 21 CFR §820.70(c), each manufacturer of a medical device, such as defendants, shall establish and maintain procedures to adequately control environmental

conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including the necessary equipment, is adequate and functioning properly.

76. Pursuant to 21 CFR §820.70(e), each manufacturer of a medical device, such as defendants, shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

**FIRST CAUSE OF ACTION:**

**STRICT PRODUCTS LIABILITY – DEFECTIVE MANUFACTURING**

77. Plaintiffs hereby incorporate by reference, as is fully set forth herein, each and every allegation set forth in the preceding paragraphs.

78. Defendants are the designer, manufacturer, distributer, seller, and/or supplier of the Recalled Devices.

79. The Recalled Devices that defendants designed, manufactured, sold, distributed, supplied and/or placed in the stream of commerce were defective in their manufacture, construction, or composition when they left the hands of defendants in that they deviated in a material way from defendants' approved product specifications, defendants' approved manufacturing performance standards, and/or other applicable federal requirements for the Recalled Devices, posing a serious risk of medical device failure and associated medical treatment, including surgical procedures to remove the Recalled Devices and replace them with non-defective cochlear implant medical devices.

80. As a direct and proximate result of plaintiff's use of defendants' Recalled Devices as manufactured, designed, sold, supplied and introduced into the stream of commerce by

defendants and/or defendants' failure to comply with federal law, plaintiff suffered serious physical injury, harm, damages, economic loss and will continue to suffer such harm, damages, and economic loss in the future.

81. Defendants' acts or omissions as alleged in this Complaint constitute an utter disregard for human safety, warranting the imposition of punitive damages.

**SECOND CAUSE OF ACTION:**

**STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

82. Plaintiffs hereby incorporate by reference, as is fully set forth herein, each and every allegation set forth in the preceding paragraphs.

83. Defendants are the designer, manufacturer, distributer, seller, and/or supplier of the Recalled Devices.

84. The Recalled Devices, as manufactured and supplied by defendants, were defective in design or formulation in that, when they left the hands of the defendants, the foreseeable risks of harm posed by the Recalled Devices were more dangerous than an ordinary consumer would expect, because they failed to comply with federal requirements for these medical devices.

85. The foreseeable risks associated with the design or formulation of the Recalled Device include, but are not limited to, the fact that the design or formulation of the Recalled Device is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

86. As a direct and proximate result of plaintiff's use of the Recalled Devices, as designed, manufactured, sold, supplied, marketed and introduced into the stream of commerce by defendant and/or defendants' failure to comply with federal requirements, plaintiff suffered

serious physical injury, harm, damages, economic loss and will continue to suffer such harm, damages and economic loss in the future.

87. Defendants' acts or omissions as alleged in this Complaint demonstrate an utter disregard for human safety, warranting the imposition of punitive damages.

**THIRD CAUSE OF ACTION:**

**STRICT PRODUCTS LIABILITY-**

**DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS**

88. Plaintiffs hereby incorporate by reference, as is fully set forth herein, each and every allegation set forth in the preceding paragraphs.

89. Defendants are the designer, manufacturer, distributer, seller, and/or supplier of the Recalled Devices.

90. The Recalled Devices as manufactured and supplied by defendants were defective in that, when they left the hands of defendants, they did not conform to representations made by defendants concerning the product and that they failed to comply with applicable federal requirements.

91. Plaintiffs and/or their physicians justifiably relief upon defendants' use of the Recalled Devices, and plaintiffs' reliance on defendants' representations regarding the character and quality of the Recalled Devices and defendants' failure to comply with federal requirements., plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

92. Defendants' acts or omissions as alleged in this Complaint constitute an utter disregard for human safety, warranting the imposition of punitive damages.

**FOURTH CAUSE OF ACTION:**

## FAILURE TO WARN

93. Plaintiffs hereby incorporate by reference, as is fully set forth herein, each and every allegation set forth in the preceding paragraphs.

94. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Recalled Devices, and in the course of the same directly advertised or marketed the product to health care professionals and consumers, including plaintiffs or persons responsible for plaintiffs, and therefore had a duty to warn of the risks associated with the use of the Recalled Devices.

95. Defendants failed to adequately warn health care professionals and the public, including plaintiff, including their prescribing physician, of the true risks of the Recalled Devices, including the propensity to fail, causing pain and suffering and requiring further treatment, including surgery.

96. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Recalled Devices. Had it done so, proper warnings would have been heeded and no health care professional, including plaintiff's physician(s) would have implanted the Recalled Devices.

97. The Recalled Devices were defective due to inadequate post-marketing warnings regarding the increased risk of failure resulting in pain and suffering and the need for surgery, while knowing that a safer alternative design existed.

98. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

99. As a direct and proximate result of the conduct of the defendant, plaintiffs suffered serious and permanent non-economic and economic injuries.

100. Defendants' conduct, as described above, was reckless. Defendants risked the lives and health of consumers and users of the Recalled Devices, including Plaintiff with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made a conscious decision not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' actions and omissions as alleged in this Complaint demonstrate an utter disregard for human safety, warranting the imposition of punitive damages.

## FIFTH CAUSE OF ACTION:

## NEGLIGENCE

101. Plaintiffs hereby incorporate by reference, as is fully set forth herein, each and every allegation set forth in the preceding paragraphs.

102. Defendants had a duty to exercise ordinary care in the design, formulation, testing, quality assurance, quality control, labeling, manufacture, marketing, promotion, sale and/or distribution of the Recalled Devices into the stream of commerce, including both a duty to assure that the Recalled Devices did not pose a significantly increased risk of bodily harm and adverse events, and a duty to comply with federal requirements.

103. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of the Recalled Devices into interstate commerce in that Defendant knew or should have known that the Recalled Devices had a propensity to fail and cause bodily harm and were not safe for use by consumers, because defendants failed to comply with federal requirements.

104. Defendants had a duty to exercise ordinary care in the advertising and sale of the Recalled Devices, including a duty to warn plaintiffs of the dangers associated with the Recalled Devices that were known or should have been known to defendants at the time of sale to plaintiffs.

105. Defendants failed to exercise ordinary care in the advertising and sale of the Recalled Devices by failing to warn plaintiff of the dangers associated with the Recalled Devices that were known or should have been known to defendants at the time of sale to plaintiff. Defendants failed to warn plaintiff that the Recalled Devices had a propensity to fail, cause bodily harm and would require surgical replacement.

106. Defendants had a duty to exercise ordinary care in the labeling of the Recalled Devices and failed to issue adequate pre-marketing or post-marketing warnings to doctors, plaintiffs, or the general public, regarding the propensity of the Recalled Devices to fail, cause bodily harm and require surgical replacement.

107. Defendants failed to exercise ordinary care in the labeling of the Recalled Devices and failed to issue adequate pre-marketing or post-marketing warnings to doctors, plaintiffs, or the general public, regarding the propensity of the Recalled Devices to fail, cause bodily harm and require surgical replacement.

108. Despite the fact that defendants knew or should have known that the Recalled Devices posed a serious risk of bodily harm to consumers, defendants continued to manufacture and market the Recalled Devices for use by consumers and continued to fail to comply with federal requirements.

109. Defendants knew or should have known that consumers such as plaintiff would foreseeably suffer injury as a result of defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

110. Defendants breached its duty of ordinary care to plaintiffs by failing to exercise due care under the circumstances as follows:

a. Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly, marketing, advertising, promotion, inspection, sale and/or distribution of the Recalled Devices, and/or to utilize and/or implement reasonably safe designs for them;

b. Failing to provide adequate and proper warnings to plaintiffs of the dangerous propensities of the Recalled Devices when used in a reasonably foreseeable manner;

c. Failing to conduct adequate post-marketing surveillance;

d. Failing to design, formulate, manufacture and incorporate or to reformulate the Recalled Devices with reasonable safeguards and protections against the type of injury and damage suffered by plaintiff when used in a reasonably foreseeable manner;

e. Failing to adequately prevent, identify, mitigate and fix defective designs and hazards associated with the Recalled Devices in accordance with good design practices;

f. Failing to notify and warn the plaintiffs of reported incidences of failure, necessitating surgery, personal injury attendant to the failure, thus misrepresenting the safety of the Recalled Devices;

g. Failing to make timely and adequate corrections to the manufacture, design and formulation of the Recalled Devices so as to prevent and/or minimize the problems encountered by plaintiff as a result of her use of the Recalled Devices;

h. Failing to use due care in the testing, formulation, inspection, distribution, sale and instructions regarding the product at all times prior to plaintiff's injuries having manifested themselves;

i. Continuing to promote and market the device despite its knowledge of these risks; and

j. Being otherwise careless, reckless and negligent.

111. As a direct and proximate result of defendants' acts and omissions, plaintiff had the Recalled Devices surgically implanted and has suffered serious physical injury, harm, damages and economic loss, including but not limited to undergoing surgery, pain and suffering and will continue to suffer such harm, damages and economic loss in the future.

112. Defendants' conduct as described herein was reckless. Defendants risked the life and health of plaintiff through the use of the Recalled Devices with knowledge and safety and efficacy problems and suppressed this knowledge from the general public. Upon information and belief, defendants made conscious decisions not to redesign, relabel, warn or inform the unsuspecting consuming public. Defendants' actions and omissions as alleged in this Complaint demonstrate an utter disregard for human safety, warranting the imposition of punitive damages.

## SIXTH CAUSE OF ACTION:

## BREACH OF EXPRESS WARRANTY

113. Plaintiffs hereby incorporate by reference, as is fully set forth herein, each and every allegation set forth in the preceding paragraphs.

114. Defendants expressly warranted that the Recalled Devices were a safe and effective hearing device for those patients requiring a hearing device.

115. At the time of making the express warranties, defendants had knowledge of the purpose for which the Recalled Devices were to be used and warranted the same to be, in all respects, fit, safe, effective, and proper for such purpose.

116. Plaintiff reasonably relied upon the claimed skill and judgment of defendants, their self-designated "Leading global hearing solutions company," and upon said express warranty, in electing to have the Recalled Devices surgically implanted.

117. The Recalled Devices manufactured and sold by defendants did not conform to these express representations because they caused serious injury to plaintiff when used as recommended and directed.

118. Defendants violated 21 U.S.C. §331(a) by introducing and delivering adulterated and misbranded medical devices into interstate commerce.

119. As a direct and proximate result of defendants' breach of warranty, plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**SEVENTH CAUSE OF ACTION:**

**BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

120. Plaintiffs hereby incorporate by reference, as is fully set forth herein, each and every allegation set forth in the preceding paragraphs.

121. At the time defendants designed, manufactured, marketed, sold, and distributed the Recalled Devices for use by plaintiff, defendants knew of the use for which the Recalled Devices were intended and impliedly warranted the Recalled Devices to be of merchantable

quality and safe for such use and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

122. Plaintiff and/or her physician(s) reasonably relied upon the skill and judgment of defendants as to whether the Recalled Devices were of merchantable quality and safe for the intended use and upon defendants' implied warranty as to such matters, including that they complied with all federal requirements.

123. Contrary to such implied warranty, defendants' Recalled Devices were not of merchantable quality or safe for their intended use, because the products were defective as described above, and failed to comply with federal requirements.

124. As a direct and proximate result of defendants' breach of warranty, plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**EIGHTH CAUSE OF ACTION:**

**NEGLIGENT MISREPRESENTATION**

125. Plaintiffs hereby incorporate by reference, as is fully set forth herein, each and every allegation set forth in the preceding paragraphs.

126. In the exercise of ordinary care, defendants knew or should have known that the Recalled Devices failed to comply with federal requirements for safe design and manufacture and/or were in other ways out of specification, yet defendants negligently misrepresented to plaintiff and/or her physician(s) that the Recalled Devices were safe and met all applicable design and manufacturing standards.

127. Plaintiff and/or her physician(s) reasonably relied to their detriment upon defendants' misrepresentations and omissions in its labeling, advertisements, and promotions concerning that the Recalled Devices were safe for use.

128. As a direct and proximate result of defendants' negligent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to the Recalled Devices, plaintiff used defendants' Recalled Devices and plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**NINTH CAUSE OF ACTION:**

**CONSTRUCTIVE TRUST**

129. Plaintiffs hereby incorporate by reference, as is fully set forth herein, each and every allegation set forth in the preceding paragraphs.

130. Defendants profited monetarily from its wrongful and unconscionable conduct, using artifice, concealment and questionable acts. Those profits may not in equity and good conscience be held and enjoyed by defendants.

131. Defendants' monetary profits should be impressed with a constructive trust and held by defendants in constructive trust for the benefit of plaintiff who has inequitably borne the health care costs related to the Recalled Devices caused by defendants' conduct.

132. Plaintiff is therefore entitled to compensation from defendants for past and future damages, including but not limited to, health care expenditures related to the Recalled Devices, together with interest and costs.

133. Plaintiffs are entitled to the imposition of a constructive trust against defendants for the benefit of plaintiffs in the amount of money expended to purchase the Recalled Devices,

implant the Recalled Devices, explant the Recalled Device, or that may be expended in the future for the same.

**TENTH CAUSE OF ACTION:**

**UNJUST ENRICHMENT**

134. Plaintiffs hereby incorporate by reference, as is fully set forth herein, each and every allegation set forth in the preceding paragraphs.

135. As an intended and expected result of its conscious wrongdoing as set forth herein, defendants have profited and benefited from payments plaintiff made for the Recalled Devices, payments made for surgical explantation of the Recalled Devices, and payments plaintiff made for purchase and surgical implantation of replacement hearing aid devices.

136. In exchange for payments made for the Recalled Devices, and at the time payments were made, plaintiff expected that the Recalled Devices were safe and medically effective for the condition for which they were prescribed.

137. Defendants voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of its wrongdoing, plaintiff paid for the Recalled Devices when they otherwise would have not done so.

138. Defendants' failure to provide plaintiff with the renumeration expected unjustly enriched the defendants.

139. Plaintiffs are entitled in equity to seek restitution of defendants' wrongful profits, revenues, and benefits to the extent and in the amount deemed appropriate by the Court and for such other relief as the Court deems just and proper to remedy the defendants' unjust enrichment.

WHEREFORE, plaintiffs request judgement against defendants Cochlear Limited, an Australian Public Company and Cochlear Americas Corporation, as follows:

a. Awarding plaintiffs compensatory damages in excess of the minimal jurisdiction amount for this Court, as well as punitive damages as a result of the wrongs alleged herein;

b. Imposing a constructive trust against defendants for the benefit of plaintiffs;

c. Establishing a medical monitoring program for the benefit of plaintiff;

d. Entering an injunction prohibiting defendants from communicating with plaintiffs concerning this civil action through plaintiffs' respective health care professionals;

e. Granting plaintiffs a trial by jury pursuant to Federal Rule of Civil Procedure 38(b) on all issues triable;

f. Awarding reasonable attorneys' fees and costs;

g. Awarding prejudgment and post-judgment interest; and

h. Any and all further relief, both legal and equitable, that this court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiffs hereby demand a jury trial pursuant to Federal Rule of Civil Procedure 38(b) on all issues so triable in this action.

Dated: New York, New York
September 22, 2017

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